Reply to Office Action dated February 22, 2010

## **LISTING OF THE CLAIMS**

2

This listing of the claims will replace all prior versions and listings of the claims.

1-67. (Cancelled).

68. (Previously presented) A quick release pharmaceutical composition for oral administration comprising a therapeutically and/or prophylactically active substance which has a solubility of at the most 0.1 % w/v in 0.1 N hydrochloric acid at room temperature,

the composition being in the form of a particulate composition or being based on a particulate composition, wherein either the particles of the particulate composition used in the manufacture of the composition have a mean particle size of at the most 250 micrometers, or

at least 50% w/w of the particles of the particulate composition used in the manufacture of the composition pass through a 180 micrometer sieve;

wherein the quick release pharmaceutical composition contains the active substance in contact with an alkaline substance; and

the composition, when tested in accordance with the dissolution method I defined herein employing 0.07 N hydrochloric acid as dissolution medium, releases at least 50% w/w of the active substance within the first 20 minutes of the test.

- 69. (Cancelled).
- 70. (Previously presented) A quick release pharmaceutical composition for oral administration comprising a therapeutically and/or prophylactically active substance which has a pK<sub>a</sub> value of at the most 5.5,

the composition being in the form of a particulate composition or being based on a particulate composition, wherein

either the particles of the particulate composition used in the manufacture of the composition have a mean particle size of at the most 250 micrometers, or

Reply to Office Action dated February 22, 2010

at least 50% w/w of the particles of the particulate composition used in the manufacture of the composition pass through a 180 micrometer sieve;

wherein the quick release pharmaceutical composition contains the active substance in contact with an alkaline substance; and

the composition, when tested in accordance with the dissolution method I defined herein, releases at least 50% w/w of the active substance within the first 20 minutes of the test.

- 71. (Previously presented) A composition according to claim 68 or 70, wherein the composition, when subjected to dissolution method I as defined herein employing 0.07 N hydrochloric acid as dissolution medium, releases at least 55% w/w of total amount of active substance present in the composition within the first 20 minutes of the test.
- 72. (Previously presented) A composition according to claim 68 or 70, wherein the solubility of the therapeutically and/or prophylactically active substance in 0.1 N hydrochloric acid at room temperature is at the most 0.05% w/v.
- 73-74. (Cancelled).
- 75. (Previously presented) A composition according to claim 68 or 70, further comprising at least one pharmaceutically acceptable excipient.
- 76. (Previously presented) A composition according to claim 75, wherein the at least one pharmaceutically acceptable excipient is selected from the group consisting of binders, disintegrants, fillers and diluents.
- 77. (Previously presented) A composition according to claim 76, wherein the composition comprises a filler having binding properties.
- 78. (Previously presented) A composition according to claim 77, wherein the filler having binding properties is selected from the group consisting of lactose, sugar derivatives, calcium carbonate (CaCO<sub>3</sub>), tricalcium phosphate (Ca<sub>3</sub>(PO<sub>4</sub>)<sub>2</sub>), calcium hydrogen phosphate (CaHPO<sub>4</sub>) and/or mixtures thereof.

Docket No.: 55682CON(71432)

Amendment dated November 23, 2009 Reply to Office Action dated February 22, 2010

- 79. (Previously presented) A composition according to claim 76, wherein the filler having binding properties is calcium hydrogen phosphate.
- 80. (Previously presented) A composition according to claim 76, wherein the filler having binding properties as raw material has a mean particle size of at the most 140 μm.
- 81. (Cancelled).
- 82. (Previously presented) A composition according to claim 108, wherein the alkaline substance is an antacid or an antacid-like substance selected from the group consisting of sodium hydrogen carbonate, magnesium carbonate, magnesium hydroxide and magnesium metasilicate aluminate or mixtures thereof.
- 83. (Previously presented) A composition according to claim 82, wherein the mean particle size of the antacid-like substance as raw material is at the most 250 μm.
- 84. (Cancelled).
- 85. (Previously presented) A composition according to claim 68 or 70, wherein the therapeutically and/or prophylactically active substance is a non-steroid anti-inflammatory drug substance (NSAID substance).
- 86. (Previously presented) A composition according to claim 68 or 70, wherein the therapeutically and/or prophylactically active substance is selected from the group consisting of lornoxicam, diclofenac, nimesulide, ibuprofen, piroxicam, piroxicam (betacyclodextrin), naproxen, ketoprofen, tenoxicam, aceclofenac, indometacin, nabumetone, acemetacin, morniflumate, meloxicam, flurbiprofen, tiaprofenic acid, proglumetacin, mefenamic acid, fenbufen, etodolac, tolfenamic acid, sulindac, phenylbutazone, fenoprofen, tolmetin, acetylsalicylic acid, dexibuprofen, paracetamol, and pharmaceutically acceptable salts, complexes and/or prodrugs thereof and mixtures thereof.
- 87. (Previously presented) A composition according to claim 68 or 70, wherein the therapeutically and/or prophylactically active substance is lornoxicam or a pharmaceutically acceptable salt, complex or prodrug thereof.

Amendment dated November 23, 2009 Reply to Office Action dated February 22, 2010

88. (Previously presented) A composition according to claim 68 or 70, comprising a further active drug substance.

Docket No.: 55682CON(71432)

- 89. (Previously presented) A composition according to claim 88, wherein the further active drug substance is an antidepressant, an opioid, a prostaglandine analogue, a glucocorticosteroid, a cytostaticum, a H<sub>2</sub> receptor antagonist, a proton pump inhibitor and/or an antacidum.
- 90. (Previously presented) A composition according to claim 88, wherein the further active drug substance is misoprostol, methotrexate, cimetidine, ranitidine, pantoprazole, omeprazole, lansoprazole, paracetamol, penicillaminutese, sulfasalazine and/or auranorfin.
- 91. (Previously presented) A composition according to claim 68 or 70, in unit dosage form, wherein the unit dosage of the composition comprises from 1 to 32 mg of the therapeutically and/or prophylactically active substance.
- 92. (Previously presented) A composition according to claim 68 or 70 in unit dosage form, wherein the unit dosage comprises from 1 mg to 1.6 g of the therapeutically and/or prophylactically active substance.
- 93. (Previously presented) A composition according to claim 68 or 70, wherein the therapeutically and/or prophylactically active substance is lornoxicam and a unit dosage of the composition contains 1, 2, 3, 4, 8, 12, 16, 20, 24, 28, 32 or 36 mg of lornoxicam.
- 94. (Previously presented) A composition according to claim 68 or 70, wherein the water content in the composition is at the most 5% w/w determined by the LOD (loss on drying) method described herein.
- 95. (Previously presented) A composition according to claim 68 or 70, comprising sodium hydrogen carbonate.
- 96. (Previously presented) A composition according to claim 68 or 70, comprising calcium hydrogen phosphate.
- 97-107. (Cancelled)

Docket No.: 55682CON(71432)

- 108. (Currently amended) A composition according to claim <u>81</u> <del>82</del>, wherein the alkaline substance is an antacid or an antacid-like substance.
- 109. (Previously presented) A composition of claim 68 or 70, wherein when tested according to the dissolution method I defined herein employing 0.07 N hydrochloric acid as dissolution medium, releases at least 80% w/w of the active substance within the first 20 minutes of the test.
- 110. (Cancelled).
- 111. (Previously presented) A composition of claim 68 or 70, wherein the quick release pharmaceutical composition is a coated tablet.
- 112-114. (Cancelled)
- 115. (Previously presented) The composition of claim 68, comprising Lornoxicam, sodium hydrogen carbonate, microcrystalline cellulose, calcium hydrogen phosphate anhydrous, L-HPC, hydroxy propyl cellulose, water, ethanol, and calcium stearate.
- 116. (Previously presented) The composition of claim 68, comprising Lornoxicam, sodium hydrogen carbonate, microcrystalline cellulose, calcium hydrogen phosphate anhydrous, L-HPC, hydroxy propyl cellulose, and calcium stearate.
- 117. (Previously presented) The composition of claim 70, comprising Lornoxicam, sodium hydrogen carbonate, microcrystalline cellulose, calcium hydrogen phosphate anhydrous, L-HPC, hydroxy propyl cellulose, water, ethanol, and calcium stearate.
- 118. (Previously presented) The composition of claim 70, comprising Lornoxicam, sodium hydrogen carbonate, microcrystalline cellulose, calcium hydrogen phosphate anhydrous, L-HPC, hydroxy propyl cellulose, and calcium stearate.
- 119. (Previously presented) The composition of claim 68, wherein the composition has a mechanical strength to enable the composition to be coated using traditional coating equipment.

Reply to Office Action dated February 22, 2010

Docket No.: 55682CON(71432)

(Previously presented) The composition of claim 70, wherein the composition 120. has a mechanical strength to enable the composition to be coated using traditional coating equipment.

- (Previously presented) The composition of claim 68, further comprising a filler having binding properties, wherein the composition comprising the binder in the form of tablets having a diameter of 9.5 mm when subjected to a crushing strength test in accordance with Ph. Eur. has a crushing strength of at least about 50N.
- (Previously presented) The composition of claim 70, further comprising a filler having binding properties, wherein the composition comprising the binder in the form of tablets having a diameter of 9.5 mm when subjected to a crushing strength test in accordance with Ph. Eur. has a crushing strength of at least about 50N.
- (Previously presented) The composition of claim 68, wherein at least 50% w/w of the particles of the particulate composition used in the manufacture of the composition pass through a 180 micrometer sieve.
- (Previously presented) The composition of claim 70, wherein at least 50% w/w of the particles of the particulate composition used in the manufacture of the composition pass through a 180 micrometer sieve.
- (Previously presented) The composition of claim 68, wherein the particles of the particulate composition comprises a granulate.
- (Previously presented) The composition of claim 70, wherein the particles of the particulate composition comprises a granulate.